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Remarks

The Applicants respectfully request that the application be reconsidered in view of the above amendment and following remarks.

The Applicants' invention is an anti-microbial composition, and more particularly to a contact anti-microbial such as quaternary ammonium, pyridinium, and phosphonium salts covalently bound to a polymeric matrix that may be suitable in a variety of applications such as film and container packaging of foodstuffs, cosmetics, medical equipment and devices, environmental, hygienic and sanitary applications, as well as other consumer and commercial use. The Applicant's invention has at least one antimicrobial side chain emanating from a synthetic organic polymer matrix such that the antimicrobial side chain is covalently bound to the synthetic organic polymer matrix.

Applicants have added new claim 41 and 42. Support for the added claims can be found in the specification within paragraph 27, where it states, "the antimicrobial material is selected from benzalkonium halide compounds . . ."

Applicants would like to thank the Examiner for his participation in a telephone interview with the Applicants on April 16, 2003 where Applicants and Examiner were able to come to an agreement with respect to the objections raised in the December 18, 2003 office action. To date, Applicants have not received an interview summary, however, Applicants understand the following agreements were made:

First, Applicants agreed to remove "or complexed" from claim 36, and the Examiner agreed to remove the Creasy reference in light of Applicants' contention that the claimed invention requires a covalent bond. By way of amendment submitted herein, Applicants removed "or complexed" from claim 36, and all objections in light of Creasy are obviated.

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Second, based upon Applicants statement that the scope of claim 37 is clear to one of ordinary skill in the art, Applicants understand that the Examiner has agreed that the parenthetical statement in claim 37 is suitable language that clearly defines the scope of the claim. The Applicants are allowed to be their own lexicographer. A parenthetical is normally used in English for amplifying or as an explanatory word, phrase, or sentence inserted in a passage from which it is usually set off by punctuation. Applicants maintain that a parenthetical expression distinctly claims the subject matter, which Applicants regard as the invention.

Applicants further add that claim 37 is in proper Markush format and submits that should the parenthetical be objected to for double inclusion, double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. Rather, the facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim renders that claim indefinite. The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear. For example, the Markush group, "selected from the group consisting of amino, halogen, nitro, chloro and alkyl" should be acceptable even though "halogen" is generic to "chloro." See e.g. MPEP 2173.05(h). In the present case, the Markush group in claim 37 includes "polyethylene terephthalate, polyethylene terephthalate (glycol modified)." Applicant submits that the scope of the claim is clear to one of ordinary skill in the art. Reconsideration is respectfully requested.

Claims 36-40 were rejected under 35 U.S.C. §102 (b) as anticipated by Creasy. As stated above, in light of this amendment, all objections to Creasy are obviated.

Claims 36-40 stand rejected under 35 U.S.C. §102 (b) as anticipated by Sawan. The Applicants respectfully disagree with the Examiner for the following reasons: In order to anticipate a claim pursuant to 35 U.S.C. § 102 (b), the reference must teach every element of the claim. Sawan fails to do so. Similar to Creasy, Sawan complexes a biocide

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to a matrix. Accordingly, the Amendment to claim 36 removing "or complexed" obviates the objection.

Moreover, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Sawan relates to formulations containing antimicrobial material, which is a combination of an organic matrix having biocidal metallic materials associated with the matrix. When a microorganism contacts the article, device, or formulation, the biocidal metallic material is <u>transferred</u> to the microorganism in amounts sufficient to kill it.

First, claim 36 as amended requires, among other things, a synthetic organic polymer matrix having covalently bound thereto a contact-killing, non leaching, charged antimicrobial side chain. Therefore, the claimed invention requires that the antimicrobial be covalently bound to the synthetic organic polymer matrix. Support for this amendment may be found in Fig. 1 where R_5 and R_9 are shown bound together by a robust covalent bond. Nowhere does Sawan disclose a side chain capable of killing microbes that is covalently bound to a matrix. Moreover, Sawan does not teach that a benzalkonium chloride is attached to the organic matrix. There is no reference to benzalkonium being in a polymer, for in and of itself it is not polymerizable, or cross-linkable. Sawan relates to materials which may be useful for 1) reversibly binding or complexing with a bactericide, and 2) insinuating the bactericide into the cell membrane of the microorganism. See Col. 8, Ins. 23 to 26. The biocide of Sawan "non-leachably binds" to or "complexes" with the organic matrix, but when placed in contact with the microorganism, preferen-

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tially transfers the biocide to the microorganism. See Col. 9, lines 24+. Sawan further mentions that metallic materials are the preferred biocide. It is respectfully submitted that Sawan discloses a biocide (antimicrobial) which is merely complexed to the matrix. Conversely, the claimed invention requires the antimicrobial to be covalently bound to the matrix. Since Sawan fails to disclose an antimicrobial ingredient covalently bound to the matrix, Sawan does not anticipate the claimed invention.

Similarly, claim 36 as amended requires, among other things, a synthetic organic polymer matrix having covalently bound thereto a contact-killing, non leaching, antimicrobial side chain. Therefore, claim 36 requires that the side chain is the antimicrobial, which acts as an antimicrobial while being bound to, and not leaching from, the synthetic organic polymer matrix. This is more clearly demonstrated by examining FIGS. 8A and 8B, which shows that the antimicrobial side chain, when in prolonged contact with the microbe kills the cell while being attached to the polymer matrix. Conversely, Sawan teaches that the antimicrobial is transferred to the microbe, i.e. leaching.

Sawan demonstrates the release of the antimicrobial agent from the surface: for example, in Column 9, lines 24+, Sawan teaches away from the claimed invention by teaching that the biocidal material . . . when placed in contact with the microorganism, preferentially transfers to the microorganism. The claimed invention utilizes an antimicrobial side chain that does not transfer to the microorganism or break away from the matrix in order to act as an antimicrobial, i.e. leach. Furthermore, Sawan Column 2, lines 39 to 43, states "selective transfer of one component from within the matrix directly to the microorganism upon contact is achieved via a 'hand off' mechanism upon engagement and penetration of the microorganism's cell membrane. Nothing in Sawan suggests the use of a contact killing, non-leaching, antimicrobial side chain as required by claim 36. Accordingly, Sawan does not teach each and every element of claim 36, and the claimed invention is not anticipated or obvious in light of Sawan.

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In Column 9, lines 24+, Sawan teaches away from the claimed invention by teaching that the biocidal material . . . when placed in contact with the microorganism, preferentially transfers to the microorganism. The claimed invention utilizes an antimicrobial side chain, which kills microbes while bound to the matrix. Such side-chains do not completely transfer to the microorganism as described in Sawan. Since, Sawan teaches away from the present invention, there is no suggestion to modify Sawan to covalently bind the antimicrobial. Accordingly the claimed invention is not obvious.

By way of this amendment, new claims 41 and 42 are added. It is respectfully submitted that claims 36, 37, 38, 39, 40, 41, and 42, all of the claims remaining in the application, are in order for allowance, and early notice to that effect is respectfully requested.

If the Examiner has any questions about this Amendment he is invited to call Michael Krenicky at (203) 324-6155.

Respectfully submitted,

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